

EXHIBIT G

Manual of PATENT EXAMINING PROCEDURE

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Additions to the text of the Manual are indicated by arrows (><) inserted in the text. Deletions are indicated by a single asterisk (*) where a single word was deleted and by two asterisks (**) where more than one word was deleted. The use of three or five asterisks in the body of the laws, rules, treaties, and administrative instructions indicates a portion of the law, rule, treaty, or administrative instruction which was not reproduced.

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701 Statutory Authority for Examination

35 U.S.C. 131. Examination of application.

The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor.

The main conditions precedent to the grant of a patent to an applicant are set forth in 35 U.S.C. 101, 102 and 103.

35 U.S.C. 101. Inventions patentable.

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Form paragraph 7.04 copies 35 U.S.C. 101. See MPEP § 706.03(a).

35 U.S.C. 100. Definitions.

When used in this title unless the context otherwise indicates -

(a) The term "invention" means invention or discovery.

(b) The term "process" means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

(c) The terms "United States" and "this country" mean the United States of America, its territories and possessions.

(d) The word "patentee" includes not only the patentee to whom the patent was issued but also the successors in title to the patentee.

(e) The term "third-party requester" means a person requesting ex parte reexamination under section 302 or *inter partes* reexamination under section 311 who is not the patent owner.

702 Requisites of the Application [R-3]

When a new application is assigned in the Technology Center, the examiner should review the contents of the application to determine if the application meets the requirements of 35 U.S.C. 111(a). Any matters affecting the filing date or abandonment of the application, such as lack of an oath or declaration, filing fee, or claims should be checked **. For Image File Wrapper (IFW) processing, see IFW Manual sections 3.1 and 3.3.

The examiner should be careful to see that the application meets all the requisites set forth in MPEP Chapter 600 both as to formal matters and as to the completeness and clarity of the disclosure. If all of the requisites are not met, applicant may be called upon

716.01(b)

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147, 87 USPQ 303 (1950). See *Dann v. Johnston*, 425 U.S. 219, 226 n.4, 189 USPQ 257, 261 n. 4 (1976).

Examiners must consider comparative data in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims. *In re Margolis*, 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986). The lack of objective evidence of nonobviousness does not weigh in favor of obviousness. *Miles Labs. Inc. v. Shandon Inc.*, 997 F.2d 870, 878, 27 USPQ2d 1123, 1129 (Fed. Cir. 1993), *cert. denied*, 127 L. Ed. 232 (1994). However, where a *prima facie* case of obviousness is established, the failure to provide rebuttal evidence is dispositive.

716.01(b) Nexus Requirement and Evidence of Nonobviousness**TO BE OF PROBATIVE VALUE, ANY SECONDARY EVIDENCE MUST BE RELATED TO THE CLAIMED INVENTION (NEXUS REQUIRED)**

The weight attached to evidence of secondary considerations by the examiner will depend upon its relevance to the issue of obviousness and the amount and nature of the evidence. Note the great reliance apparently placed on this type of evidence by the Supreme Court in upholding the patent in *United States v. Adams*, 383 U.S. 39, 148 USPQ 479 (1966).

To be given substantial weight in the determination of obviousness or nonobviousness, evidence of secondary considerations must be relevant to the subject matter as claimed, and therefore the examiner must determine whether there is a nexus between the merits of the claimed invention and the evidence of secondary considerations. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 305 n.42, 227 USPQ 657, 673-674 n. 42 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986). The term "nexus" designates a factually and legally sufficient connection between the objective evidence of nonobviousness and the claimed invention so that the evidence is of probative value in the determination of nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing*

Ltd., 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir.), *cert. denied*, 488 U.S. 956 (1988).

716.01(c) Probative Value of Objective Evidence [R-2]

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I. < TO BE OF PROBATIVE VALUE, ANY OBJECTIVE EVIDENCE SHOULD BE SUPPORTED BY ACTUAL PROOF

Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence." "[A]ppellants have not presented any experimental data showing that prior heat-shrinkable articles split. Due to the absence of tests comparing appellant's heat shrinkable articles with those of the closest prior art, we conclude that appellant's assertions of unexpected results constitute mere argument."). See also *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972); *Ex parte George*, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991).

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II. < ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE

The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

EXAMINATION OF APPLICATIONS

716.01(d)

See MPEP § 2145 generally for case law pertinent to the consideration of applicant's rebuttal arguments.

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III. < OPINION EVIDENCE

Although factual evidence is preferable to opinion testimony, such testimony is entitled to consideration and some weight so long as the opinion is not on the ultimate legal conclusion at issue. While an opinion as to a legal conclusion is not entitled to any weight, the underlying basis for the opinion may be persuasive. *In re Chilowsky*, 306 F.2d 908, 134 USPQ 515 (CCPA 1962) (expert opinion that an application meets the requirements of 35 U.S.C. 112 is not entitled to any weight; however, facts supporting a basis for deciding that the specification complies with 35 U.S.C. 112 are entitled to some weight); *In re Lindell*, 385 F.2d 453, 155 USPQ 521 (CCPA 1967) (Although an affiant's or declarant's opinion on the ultimate legal issue is not evidence in the case, "some weight ought to be given to a persuasively supported statement of one skilled in the art on what was not obvious to him." 385 F.2d at 456, 155 USPQ at 524 (emphasis in original)).

In assessing the probative value of an expert opinion, the examiner must consider the nature of the matter sought to be established, the strength of any opposing evidence, the interest of the expert in the outcome of the case, and the presence or absence of factual support for the expert's opinion. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986). See also *In re Oelrich*, 579 F.2d 86, 198 USPQ 210 (CCPA 1978) (factually based expert opinions on the level of ordinary skill in the art were sufficient to rebut the *prima facie* case of obviousness); *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (statement in publication dismissing the "preliminary identification of a human b-NGF-like molecule" in the prior art, even if considered to be an expert opinion, was inadequate to overcome the rejection based on that prior art because there was no factual evidence supporting the statement); *In re Carroll*, 601 F.2d 1184, 202 USPQ 571 (CCPA 1979) (expert opinion on what the prior art taught, supported by documentary evidence and formulated prior to the making of the claimed invention, received considerable deference); *In re Beattie*,

974 F.2d 1309, 24 USPQ2d 1040 (Fed. Cir. 1992) (declarations of seven persons skilled in the art offering opinion evidence praising the merits of the claimed invention were found to have little value because of a lack of factual support); *Ex parte George*, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991) (conclusory statements that results were "unexpected," unsupported by objective factual evidence, were considered but were not found to be of substantial evidentiary value).

Although an affidavit or declaration which states only conclusions may have some probative value, such an affidavit or declaration may have little weight when considered in light of all the evidence of record in the application. *In re Brandstadter*, 484 F.2d 1395, 179 USPQ 286 (CCPA 1973).

An affidavit of an applicant as to the advantages of his or her claimed invention, while less persuasive than that of a disinterested person, cannot be disregarded for this reason alone. *Ex parte Keyes*, 214 USPQ 579 (Bd. App. 1982); *In re McKenna*, 203 F.2d 717, 97 USPQ 348 (CCPA 1953).

716.01(d) Weighing Objective Evidence [R-6]

IN MAKING A FINAL DETERMINATION OF PATENTABILITY, EVIDENCE SUPPORTING PATENTABILITY MUST BE WEIGHED AGAINST EVIDENCE SUPPORTING *PRIMA FACIE* CASE

When an applicant timely submits evidence traversing a rejection, the examiner must reconsider the patentability of the claimed invention. The ultimate determination of patentability must be based on consideration of the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The submission of objective evidence of patentability does not mandate a conclusion of patentability in and of itself. *In re Chupp*, 816 F.2d 643, 2 USPQ2d 1437 (Fed. Cir. 1987). Facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion of a *prima facie* case was reached, not against the conclusion itself. *In re Eli Lilly*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990). In other words, each piece of rebuttal evidence